REMARKS

Reconsideration and withdrawal of the rejections of the pending claims are respectfully requested in view of the remarks herein, which place the application in condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

The specification has been amended to clarify a clerical error in paragraph [0040] in the application as published. Specifically, the published application recites, "Examples of organic solvents include but are limited to...." This has been amended to correctly recite, "Examples of organic solvents include but are not limited to..." This is clearly an *In re Oda* situation as the full text of paragraph [0040] reads:

> Examples of organic solvents include but are limited to straight chain or branched alcohols such as methyl alcohol, ethyl alcohol, propyl alcohol, butyl alcohol, isopropyl alcohol and the like, other solvents include but are not limited to benzylbenzoate, Crodamol, miglyol, ethylene glycol, propylene glycol, polyethylene glycol, glycerol, glycerol formal, N-methyl pyrrolidone, sorbitol, pentaerythriol, and the like.

The Examiner is respectfully reminded of MPEP 2163.07, section II which refers to correcting obvious errors: "An amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of error in the specification, but also the appropriate correction. *In re Oda*, 443 F.2d 1200, 170 USPQ 268 (CCPA 1971)."

Claims 1, 2, 4-7, and 9-24 remain pending in this application.

Claims 3 and 8 have been cancelled.

Claims 1 and 13 have been amended to clarify the ranges of avermectin compound, wax and additional stabilizer. Support for the range clarifications of the avermectin compound and wax can be found, for example, in the provisional application (US 60/530,939; "the '939 application") on page 6. Support for the range clarification of additional stabilizer in claim 1 can be found, for example, in the '939 application on page 20, claim 17. Support for the range clarification of additional citric acid in claim 13 can be found, for example, in the '939 application on page 9, ¶ 1, and in claims 12 and 17 of the '939 application.

Claim 14 has been amended to recite "wherein" for clarification related to a clerical error.

Claims 14 and 19 have been amended to clarify the range for the stabilizer, support for which can be found, for example, on page 9, ¶ 1, and in claims 12 and 17 of provisional application (US 60/530,939).

Claim 18 has been amended to delete the recitation of milbemycin. Applicants note that this amendment was presented in the previous response, however the claim identifier did not recite that the claim was amended. Thus, the claim identifier has been corrected in this response to reflect the amended claim.

Claim 24 has been amended to clarify the percentages of the components in parts a) and b) in the premix, support for which can be found, for example, on page 6 of the provisional application. Support for the recitation of "a mixture thereof" in part iii) of claim 24 can be found, for example, on page 6 of the provisional application. Support for the clarification of the amount of citric acid in part d) of claim 24 can be found, for example, on pages 9-10 of the provisional application (US 60/530,939).

No new matter has been added.

The Examiner is thanked for withdrawal of all previous rejections not reiterated in the pending Action.

It is submitted that the amendments of the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112. Rather, these amendments are made simply for clarification.

The issues raised by the Examiner in the Office Action are addressed below in the order presented in the Action.

II. PRIORITY OF THE APPLICATION

The Examiner maintains that the instant application is not entitled to the benefit of priority of the provisional application filed December 19, 2003 (60/530939), particularly mentioning that it does not provide support for the pH of the premix of claim 8, the ranges of ingredients recited in claim 13, and the recitation of citric acid in about 0.3 to about 0.4% propylene glycol in claim 24 of the pending application.

Claim 8 has been canceled in the amendment submitted herewith.

Claims 1, 13, 14, 19, and 24 have been amended to conform the ranges of specific ingredients to those disclosed in the provisional application, and are specifically found, for example, on pages 6, 9, 10, and 19-21 of the provisional application as filed. The recitation of the concentrations each of these components in the '939 application is consistent with those recited in the present application.

Thus, the claims of subject application as amended herein are reflective of the ranges of the ingredients recited in the provisional application, and the applicants request confirmation as to the priority date of December 19, 2003, which is the filing date of U.S. Provisional Application No. 60/530,939, the '939 application.

III. THE REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, ARE OVERCOME

Claims 13 and 24 remain rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner contends that support for the ranges of ingredients is not clearly provided in the provisional application, and that the original amount of citric acid is not distinguished from the additional amount. Furthermore, the Examiner notes that preferred amounts of the stabilizer are in the range of about 0.3% to about 1.5%, as recited in paragraph [0041] of the published application.

As noted above in Section II, claim 13 as amended conforms to the ranges of ingredients provided in the provisional application. Support for these ranges can be found, for example on pages 6, 9, 10, and 19-21 of the provisional application. The provisional application recites "determination of an amount of stabilizer effective to decrease or prevent the acid or base catalyzed degradation....is determined by adding small amounts of stabilizers in addition to that amount normally added...Preferred amounts of the stabilizer range from about 0.3 to about 1%...Most preferably the amount of stabilizer added is about 0.5% (w/w)" in paragraph 1 of page 9." Thus, the range of the additional stabilizer as recited in claim 13 currently amended is fully supported by the provisional application. This is also supported in paragraph [0041] of the nonprovisional application as published.

Claim 24 has been amended to remove the recitation of ranges, and to provide values for each component that are within the ranges provided in the provisional application on, for example, pages 6, 9, 10, and 19-21.

Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. §112, first paragraph, are respectfully requested.

IV. THE REJECTIONS UNDER 35 U.S.C. § 103(a) ARE OVERCOME

Claims 1, 2, and 4-23 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Jancys et al., U.S. Patent No. 6,489,303, in view of Katoh et al., U.S. Patent No. 4,939,166, Chabala et al., U.S. Patent No. 4,199,569, Sutherland et al., U.S. Patent No. 4,910,219, Freehauf et al., U.S. Patent No. 7,001,889, and Carson et al., U.S. Patent No. 6,548,478.

The Examiner portends that one skilled in the veterinary art would have been motivated to prepare a premix for an animal feed comprising at least one avermectin in combination with a pharmaceutically acceptable surfactant, wax, antioxidant, stabilizer and carrier vehicle with a reasonable expectation of having an extended shelf-life, because the problem of stability of premix compositions comprising avermectins is successfully addressed by Jancys. The Applicants respectfully disagree.

Establishing a *prima facie* case of obviousness requires that the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP 2143. The Supreme Court has recently reaffirmed the factors set out in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18: "[T]he scope and content of the prior art are determined; differences between the prior art and the claims at issue are...ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727. Furthermore, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): "The mere fact that the prior art may be modified in the manner suggested by the Office Action does not make the modification obvious unless the prior art suggests the desirability of the modification." Also, the Examiner is respectfully reminded that for the Section 103 rejection to be proper, both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants' disclosure. *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

Jancys relates to a veterinary medicament which is diluted to liquid compositions containing water (see Jancys, examples I-IV), which is distinct from a premix for an animal feed as required by the instant application. Thus, the additional citric acid or sodium citrate is added as a solution in water in order to adjust the pH of the solution to the range of 6.0 – 6.8 (example I, col. 5, ll. 12-14 of Jancys). Jancys uses the additional buffer (citric acid or sodium citrate) in the context of an aqueous dispersion, not a granular premix (Jancys col. 5, l. 7). Importantly, Jancys does not recite the amount of added citric acid or sodium citrate required. Thus, the amount of additional citrate or citric acid is not obviously inferred from Jancys.

In contrast, the present application discusses percentages of additional citric acid added to enhance shelf-life, which is further supported in the instant specification by reinforcing that the percentages of additional citric acid result in a formulation pH between about 4-6 (col. 2, l. 4 of the instant application). This is further relevant considering that the instant application relates to premixes for feeds in granular form as the carrier vehicle in the present application is selected from a variety of solids (claim 1 of the instant application). The small volume of additional stabilizer as recited in the instant application provides unexpected extension of shelf-life, which is not obvious from Jancys as Jancys teaches modification directed to a pH in a higher range than does the instant application.

Carson, as the Applicants have previously contended in a response mailed May 14, 2008, relates to a compound which is functionally and structurally unique from the avermectin family. Carson relates to virginiamycin, which is a macrocyclic peptide-based antibiotic. As shown in Figure 1, Virginiamycin has no structural similarity to the avermectin/milbemycin family (exemplified in Fig. 1 below using ivermectin), particularly with respect to the means by which decomposition can occur. As shown in the present application, decomposition of the avermectins/milbemycins occurs via epimerization and migration of the double bond between C(2) and C(3) of the bicyclic ring, or by loss of the saccharide moiety (Figures 1 and 2 of the instant application). In contrast, *the structurally distinct virginiamycin lacks both the saccharide and the bicyclic ring*. Additionally, Carson provides no instruction regarding the mechanism by which decomposition of verginiamycin is thought to occur. As a result, it would not be obvious to extend any stabilizer used with virginiamycin to an avermectin/milbemycin formulary as it would not be possible to predict the results. Thus, Carson provides no incentive to modify any of the other references in order to stabilize the avermectin/milbemycin formulation.

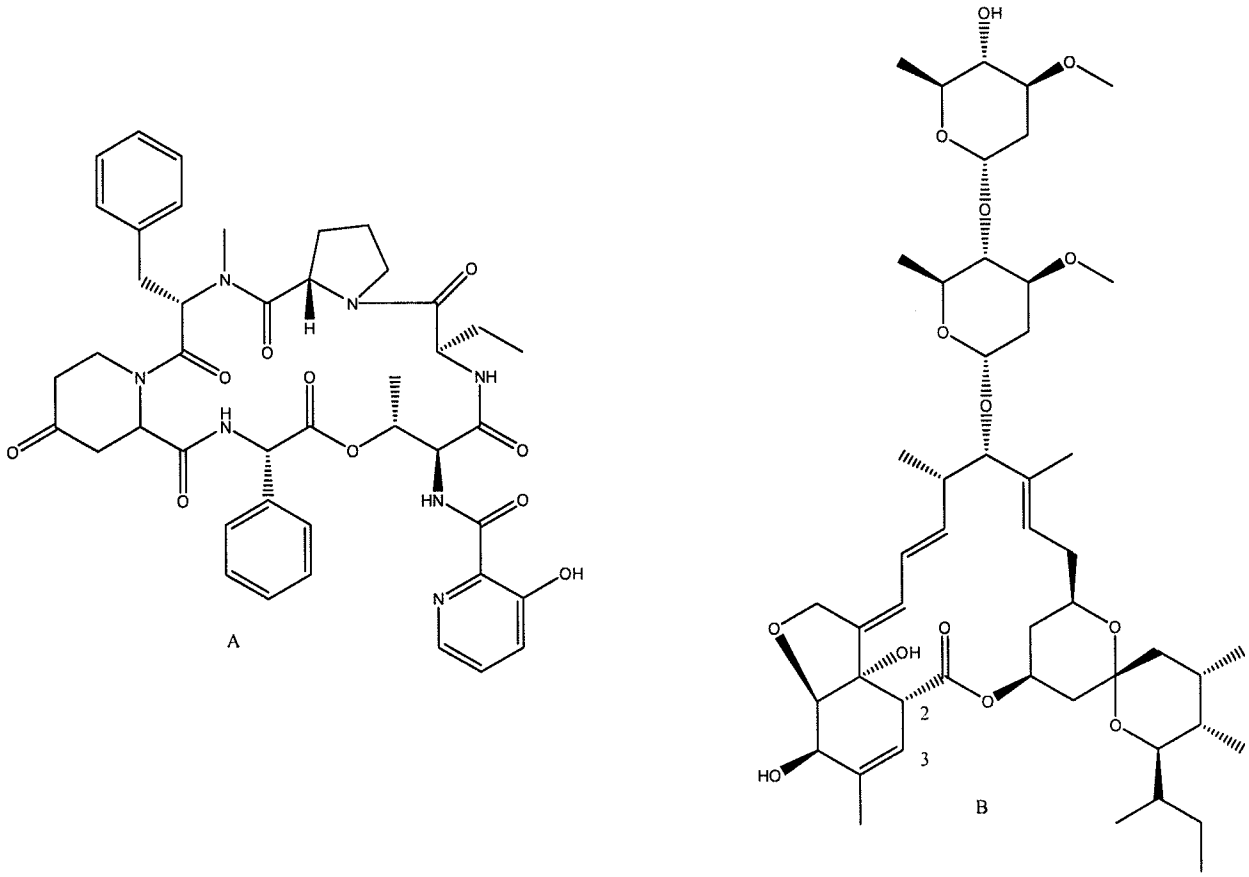

Figure 1. The chemical structures of virginiamycin S_1 (A) and ivermectin (B).

According to Carson, maintenance of pH permits suspension in an aqueous environment with minimal effect on activity (col. 2, ll. 41-43), and further shows that the mixture is designed to be added to water (see col. 2, ll. 39-43). Carson does not relate this maintenance of pH to minimization of decomposition. For example, the pH could be construed to relate to solubility of the virginiamycin in solution.

Applicants respectfully submit that Freehauf (US Patent 7,001,889) does not meet the criteria to be qualify as prior art under 35 U.S.C. §102 (e) rendering the rejection under 35 U.S.C. §103 improper.

MPEP § 706.02(k) states that

> "[e]ffective November 29, 1999, subject matter which was prior art under former 35 U.S.C. § 103 via 35 U.S.C. § 102(e) is now disqualified as prior art against the claimed invention if that subject matter and the claimed invention 'were, at the time the invention was made, owned by the same person or subject to an obligation of

> assignment to the same person.' This change to 35 U.S.C. § 103(c) applies to all utility design, and plant applications filed on or after November 29, 1999..."

The priority date of Freehauf (the '889 patent) is June 21, 2002 (filed as US application 10/177,822; the '822 application). The '822 application was published on December 25, 2003, and is assigned to Merial, Ltd. of Duluth, GA as set out at Reel 014410 and Frame 0204, recorded on August 21, 2003 at the USPTO.

The earliest effective filing date of the instant application (USSN 10/790,489; the '489 application) is December 19, 2003 (filed as US provisional application 60/530,939). The instant application is also assigned to Merial, Ltd. of Duluth, GA as set out at Reel 018030 and Frame 0175, recorded on June 27, 2006 at the USPTO.

As such, the '889 patent cannot be properly considered as a reference under 35 U.S.C. §103(a), as 35 U.S.C. §102(e) expressly forbids such a reference from "precluding patentability." This reference is not by "another," as required by Section 102(e). Accordingly, it is respectfully requested that the rejection of claims under 35 U.S.C §103(a) as being unpatentable over Freehauf (U.S. Patent 7,001,889) be withdrawn.

According to the instant claims, none of the cited references cited, either alone or in combination, teach, suggest, motivate or render obvious to try the presently claimed invention of increasing the amount of existing stabilizer in the premix in the claimed amounts in order to increase stability and shelf life of the feed.

In making an obviousness determination, the Examiner may assess evidence related to secondary indicia of non-obviousness such as ***commercial success***, copying, long felt but unsolved need, failure of others, ***unexpected results created by the claimed invention***, unexpected properties of the claimed invention, licenses showing industry respect for the invention, and skepticism of skilled artisans before the invention. *See In re Rouffet*, 149 F.3d 1350, 1355 (Fed. Cir. 1998); *see also In re Emert*, 124 F.3d 1458, 1462 (Fed. Cir. 1997) (consideration of the secondary objective indicia of nonobviousness is essential to an obviousness determination).

Finally, evidence of unexpected results must be considered in evaluating the obviousness of a claimed invention. *See Richardson-Vicks Inc. v. Upjohn Co.*, 122 F.3d 1476, 1483 (Fed.

Cir. 1997) ("evidence arising out of the so-called secondary considerations must always when present be considered en route to a determination of obviousness.").

Unexpected results are presented in Tables II and III of the present application, wherein the example is given of additional stabilizer being added to the IVOMEC premix. A small amount (between 0.3 and 1.2%) of added stabilizer provides a significant benefit with respect to minimization of degradation and extension of shelf life relative to the original IVOMEC premix. This provides a clear example of the present application addressing an unsolved problem in the context of avermectin formulations for premixes.

Regarding commercial success, as stated in the application and above, the premix formulation is used in the IVOMEC Premix manufactured and sold by Merial, Ltd. The IVOMEC Premix offers unsurpassed efficacy against a variety of parasites, and the extended shelf-life of the product is an essential component of the commercial success.

For the foregoing reasons, none of the references cited by the Examiner, either alone or in combination, render the pending claims *prima facie* obvious. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a) are respectfully requested.